

REMARKS

This is in response to the Office Action mailed on July 9, 2003 for the above-identified reissue application. A petition for extension of time to respond is filed herewith. The Examiner had objected to the disclosure and the amended drawings for certain format and clerical errors. The Examiner objected to the lack of a "Status Of Claims And Support For Claim Changes" and the oath of Anthony Kosinski (an inventor not named on the issued patent). As discussed below, these concerns are believed to be addressed.

Claims 1-29 were in the issued patent. Claims 30-77 were added in the reissue application. In this paper, Claims 39 and 59 and 75 are cancelled and claims 78-87 are newly presented. Claims 30, 45, 54, 62 and 63 are amended.

In the outstanding office action, Claims 59, 63 and 75 were rejected under 35 U.S.C §112. Claims 30-38, 43-47, 49, 50, 54-66 were rejected under 35 U.S.C. §102 or §103 in view of the prior art. The Examiner indicated that claims 1-29, 39-42, 48, 51-53 and 67-77 were free from any rejection based upon the prior art. Reconsideration of the rejected claims is respectfully requested in view of the foregoing amendments and the following remarks.

Disclosure

The Examiner objected to the Disclosure for failing to provide the corrections in both the single column and double column format. The Amendments to the Specification are set forth herein in accord with 37 C.F.R. §1.173 (b) and the form of the amendments is believed now to be appropriate.

The Examiner also questioned certain aspects of the Specification. Specifically, the Examiner questioned whether elements 334, 334, 346, 348 and 350 were used to note different structures in Figure 16 and Figure 23. Applicant respectfully notes that these numerals are used to identify the same elements, respectively, in each drawing. Element 334 refers to a cavity on the proximal end of the blade holder. Elements 344 and 346 refer to side walls of the blade holder that define the cavity 334. Element 350 defines a

groove that extends from the blade holder to the handle. Consequently, these elements are not believed to be used improperly.

The Examiner questioned the description of the depths “a” and “b” as seen in Figures 35c and 35d. The Specification has been amended to address the Examiner’s concern. Further, the Drawings have been amended to reflect the transposition of “a” and “b” in the Drawings. Consequently, this concern is believed to be addressed.

The Examiner questioned how the proximal end of the handle could contact the bosses on the shield. The Specification has been amended to reflect that the *distal* end of the handle contacts the bosses on the needle shield, as clearly depicted in the drawings.

Drawings

The Examiner objected to the Drawings for failing to indicate where changes had been made. New annotated sheets reflecting the changes are submitted herewith in the attached appendix.

Status Of The Claims And Support For The Claims

The Examiner objected to the lack of Status Of The Claims And Support For The Claims as set forth in 37 C.F.R. §1.173. A chart is submitted herewith (including changes previously made) and is believed to satisfy the requirements of 37 C.F.R. §1.173.

Reissue Declaration

The Examiner objected to the declaration of Anthony J. Kosinski for failing to mention the error incorrectly not named in an issued patent. The original declaration submitted with the reissue application named Mr. Kosinski as an inventor and included a statement, *inter alia*, that the invention as claimed was unnecessarily limited. There is no obligation to point out every error. This Declaration is therefore believed to satisfy the requirements of 37 C.F.R. §1.175. The Manual of Patent Examining Procedure points out that “The reissue application with its reissue oath or declaration under 37 CFR 1.175 provides a complete mechanism to correct inventorship. See *A.F. Stoddard & Co. v. Dann*, 564 F.2d at 567, 195 USPQ at 106.” MPEP, §1412.04. Consequently, the original declaration submitted with this reissue application is believed to be adequate and

reconsideration is respectfully requested. Further, Applicant respectfully requests reconsideration of the rejection of claims 1-77 under 35 U.S.C. §251 for the same reason. Upon final determination of the allowable claims, applicant will submit appropriate Supplemental Declarations.

35 U.S.C. §112

Claims 59, 63 and 75 were rejected under 35 U.S.C. §112. Claims 59 and 75 have been cancelled. Claim 63 has been amended to address the concerns of the Examiner and reconsideration is respectfully requested.

Aikens (U.S. Patent 4,491,132)

Claims 30-38, 43-47, 49 and 50 were rejected under 35 U.S.C. 102 and/or 35 U.S.C. §103 in view of U.S. Patent 4,491,132 to Aikens (“Aikens”). Claim 30 has been amended to include limitations similar to claim 39 (but modifying the “means to substantially prevent” such that it is not necessarily part of the shield), which had been indicated as containing allowable subject matter. Claim 45 has been amended to include a limitation similar to claim 41, which had been indicated as containing allowable subject matter. Consequently, Claims 30-38, 43-47, 49 and 50 are believed to be patentable in view of Aikens.

Werner (5,292,329)

Claims 54-66 were rejected under 35 U.S.C. 102 and/or 35 U.S.C. §103 in view of U.S. Patent 5,292,329 to Werner (“Werner”). Claim 54 is directed to a surgical scalpel including a handle having a proximal portion (which is adapted to be gripped by the clinician) and a distal portion to which a blade is attached. A groove is formed in the sidewall of the handle. A shield is mounted to the distal portion of the handle. The shield slides from a distal position, in which the blade is shielded, and a *proximal position, in which the blade is exposed but the proximal portion of the handle is not enclosed*. A latch has an inward projection disposed in the groove to releasably hold the shield in the proximal position and the distal position. This structure permits the surgeon to selectively shield and expose the blade in a true one-handed operation.

In contrast, Werner relates to a retractable surgical knife that includes a blade support assembly 44 which is telescopically positioned within a sheath 42. The sheath is not slidably mounted to the distal portion of the handle. The sheath is designed to extend distally to cover the blade when not in use. During use, however, the sheath is withdrawn over the blade support assembly to serve as the handle. Consequently, the sheath encloses the proximal portion of the blade support assembly. Indeed, the sheath may be knurled so that the surgeon can better grip the scalpel. Werner, col. 6, lines 21-23. In any event, to use such a device, the surgeon must employ two hands. Claim 54, as well as claims 55-61 which depend therefrom, are believed patentable over Werner. Werner does not teach the structure set forth in claim 54. Further, Werner operates in a very different manner (that is, the sheath is withdrawn to serve as a handle during use) such that one skilled in the art would not be disposed to modify Werner to achieve the claimed invention.

Claim 62 (as amended) is directed to a handle that may be mounted on a cartridge to form a scalpel. The handle includes a proximal hand gripping portion. An intermediate shank is connected to the proximal hand gripping portion. A tang extends from the distal end of the intermediate shank. The tang is adapted to directly engage a scalpel blade. Means are provided for connecting the handle to a cartridge. In contrast, in Werner, the “tang” (that is, the arc-shaped portions of fitting portion 98) is connected to a blade receiving portion 88 which, in turn, is attached to the blade. The inclusion of additional structure may result in additional structural instability or higher manufacturing tolerances. The structure of claim 62 allows for direct engagement between the tang and the handle, providing additional structural stability and better control for the surgeon – which, of course, is paramount. Since Werner completely fails to teach or suggest a tang adapted for this sort of direct connection to a scalpel blade, claim 62, as well as claims 66 which depend therefrom, are believed patentable over Werner.

New Claims

New claim 78 is an independent claim of scope similar to previously-presented claim 41 (which depended from previously-presented claim 30), which had been

indicated as having patentable subject matter. Claim 78 is therefore believed to be allowable.

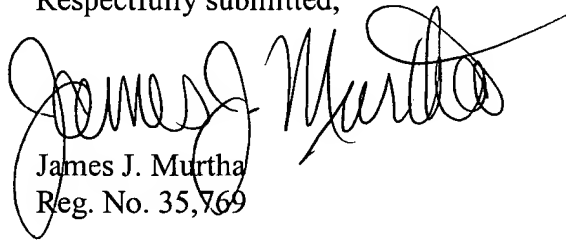
New claim 79 is an independent claim somewhat related in scope to previously-presented claim 39 (which had been indicated as having allowable subject matter). Unlike claim 39, however, claim 79 does not recite a blade holder. Rather, this claim focuses on the structural relationship between the blade and the shield – such that proximal movement of the shield with respect to the blade is prevented unless the cartridge is mounted to the handle. New claims 80-82 depend from claim 79.

New claim 83 is an independent claim somewhat related in scope to previously-presented claim 41 (which had been indicated as having allowable subject matter). Unlike claim 41, however, claim 83 does not recite a blade holder. Rather, this claim focuses on the structural relationship between the cartridge and the handle unless the shield is in the distal position. New claims 84-87 depend from claim 89.

CONCLUSION

The currently-pending claims are believed patentable in view of the prior art. The form of this reissue application is believed to be in condition for allowance. Should any issues remain outstanding, the Examiner is invited to call the undersigned.

Respectfully submitted,


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STATUS OF THE CLAIMS AND SUPPORT FOR THE CLAIMS

Claim	Change	Support in Specification
1 (Original)	None	
2 (Original)	None	
3 (Original)	None	
4 (Original)	None	
5 (Original)	None	
6 (Original)	None	
7 (Original)	None	
8 (Original)	None	
9 (Original)	None	
10 (Original)	None	
11 (Original)	None	
12 (Original)	None	
13 (Original)	None	
14 (Original)	None	
15 (Original)	None	
17 (Original)	None	
18 (Original)	None	
19 (Original)	None	
20 (Original)	None	
21 (Original)	None	
22 (Original)	None	
23 (Original)	None	
24 (Original)	None	
25 (Original)	None	
26 (Original)	None	
27 (Original)	None	
28 (Original)	None	
29 (Original)	None	

<u>Claim</u>	<u>Change</u>	<u>Support in Specification</u>
30 (Amended)	New claim directed to a cartridge with a blade holder, blade and shield with means to substantially prevent proximal movement of shield with respect to blade holder unless cartridge is mounted to handle.	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
31 (Previously presented)		Depends from Claim 30
32 (Previously presented)		Depends from Claim 30
33 (Previously presented)		Depends from Claim 30
34 (Previously presented)		Depends from Claim 30
35 (Previously presented)		Depends from Claim 30
36. (Previously presented)		Depends from Claim 30
37. (Previously presented)		Depends from Claim 30
38 (Previously presented)		Depends from Claim 30
39 (Cancelled)		Depends from Claim 30
40 (Previously presented)		Depends from Claim 30
41 (Previously presented)		Depends from Claim 30
42 (Previously presented)		Depends from Claim 30
43 (Previously presented)		Depends from Claim 30
44 (Previously presented)		Depends from Claim 30
45 (Amended)	New claim directed to a cartridge having a blade holder, a blade attached to the blade holder and a shield slidably mounted on said blade holder, means for releasably mounting said blade holder to a handle, means to prevent dismounting the blade holder from a handle unless the shield is in the distal position.	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10

<u>Claim</u>	<u>Change</u>	<u>Support in Specification</u>
46 (Previously presented)		See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
47 (Previously presented)		See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
48 (Previously presented)		See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
49 (Previously presented)		See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
50 (Previously presented)		See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
51 (Previously presented)	New claim directed to a cartridge comprising a blade holder, a blade attached to the blade holder, a shield slidably mounted on said blade holder and a latch that substantially prevents proximal movement of the shield with respect to the blade holder unless the cartridge is mounted to a handle.	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
52 (Previously presented)		Depend from Claim 51
53 (Previously presented)		Depend from Claim 51

Claim	Change	Support in Specification
54 (Amended)	New claim directed to a surgical scalpel having a handle adapted to be gripped by a clinician during use, a blade attached to the handle adjacent to the distal portion of the handle and a shield slidably mounted to the handle along the distal portion of the handle so as to be movable between a distal position shielding the blade and a proximal position exposing the blade for use without enclosing the proximal portion of the handle. A latch is associated with the shield and has an inward projection disposed in the groove to releasably hold the shield in the distal position and the proximal position.	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
55 (Previously presented)		Depend from Claim 54
56 (Previously presented)		Depend from Claim 54
57 (Previously presented)		Depend from Claim 54
58 (Previously presented)		Depend from Claim 54
59 (Cancelled)	Cancelled	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
60 (Previously presented)		Depend from Claim 54
61 (Previously presented)		Depend from Claim 54

<u>Claim</u>	<u>Change</u>	<u>Support in Specification</u>
62 (Amended)	New claim directed to a handle including a proximal hand gripping portion having a distal end, an intermediate shank having a proximal end and a distal end connected at its proximal end to the distal end of the proximal hand gripping portion; a tang extending from a distal end of the intermediate shank adapted to be directly engaged to a scalpel blade; and a means for releasably connecting the handle to a cartridge.	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
63 (Amended)	Clarify that downwardly extending projection is part of connecting means	Depend from Claim 62
64 (Previously presented)		Depend from Claim 62
65 (Previously presented)		Depend from Claim 62
66 (Previously presented)		Depend from Claim 62

Claim	Change	Support in Specification
67 (Previously presented)	New claim directed to a surgical scalpel, comprising: a handle having a proximal hand gripping portion having a distal end, an intermediate shank having a proximal end and a distal end connected at its proximal end to the distal end of the proximal hand gripping portion wherein the intermediate shank defines a substantially longitudinally extending groove therein, and a tang extending from a distal end of the intermediate shank; a cartridge releasably mounted on the handle to form a scalpel including a blade holder with a proximal end and a distal end and a blade attached to said blade holder wherein the blade holder defines a substantially longitudinally extending groove therein aligned with the groove formed in the intermediate shank; and a shield slidably mounted about the cartridge so as to be movable between a distal position shielding the blade and a proximal position exposing the blade for use and having a latch associated with the shield and having an inward projection disposed in the groove to releasably hold the shield in the distal position and the proximal position.	See, e.g., Figs. 25-36c; col. 9, line 37-col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
68 (Previously presented)		Depend from Claim 67
69 (Previously presented)		Depend from Claim 67
70 (Previously presented)		Depend from Claim 67
71 (Previously presented)		Depend from Claim 67
72 (Previously presented)		Depend from Claim 67
73 (Previously presented)		Depend from Claim 67
74 (Previously presented)		Depend from Claim 67
75 (Cancelled)	Cancelled	
76 (Previously presented)		Depend from Claim 67
77 (Previously presented)		Depend from Claim 67

Claim	Change	Support in Specification
78 (Newly presented)	New claim directed to a cartridge that may be mounted on a handle to form a scalpel, comprising: a blade holder with a proximal end, a distal end and an external surface; a blade attached to said blade holder; a shield slidably mounted about said blade holder so as to be disposed about the external surface of the blade holder wherein the shield is movable between a distal position shielding the blade and a proximal position exposing the blade for use; and means to prevent dismounting the cartridge from a handle unless the shield is in the distal position.	See, e.g., Figs. 25-36c; col. 9, line 37- col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
79 (Newly presented)	New claim directed to a scalpel comprising: a handle; and a cartridge selectively attached to the handle and including: a shield; and a blade operably connected to the shield for relative sliding movement such that the shield is movable between a distal position shielding the blade and a proximal position exposing the blade for use and proximal movement of the shield with respect to the blade is prevented unless the cartridge is mounted to the handle.	See, e.g., Figs. 25-36c; col. 9, line 37- col. 12, line 61 Figs. 37-40d; col. 12, line 62 – col. 17, line 10
80 (Newly presented)		Depend from Claim 79
81 (Newly presented)		Depend from Claim 79
82 (Newly presented)		Depend from Claim 79

<u>Claim</u>	<u>Change</u>	<u>Support in Specification</u>
83 (Newly presented)	New claim directed to a scalpel comprising: a handle; and a cartridge selectively mounted to the handle, the cartridge comprising: a shield; and a blade operably connected to the shield for relative sliding movement such that the shield is movable between a distal position shielding the blade and a proximal position exposing the blade for use; wherein the cartridge is lockingly engaged to the handle unless the shield is in the distal position.	
84 (Newly presented)		Depend from claim 84
85 (Newly presented)		Depend from claim 84
86 (Newly presented)		Depend from claim 84
87 (Newly presented)		Depend from claim 84

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